TCT-603

Randomized comparison of 9-month stent struts coverage of biolimus and everolimus drug-eluting stents assessed by OCT in patients with STEMI

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BACKGROUND The aim of this trial was to compare healing (assessed by optical coherence tomography-OCT) of biolimus A9 and everolimus drug-eluting stents at 9-month follow-up in patients with ST-segment elevation myocardial infarction (STEMI) treated by primary PCI (pPCI). 9-month clinical and angiographic data were also compared in both groups.

METHODS 201 patients with STEMI treated by primary PCI were randomly enrolled in the trial. 101 patients were randomized to the biolimus A9 stent group and 100 patients to the everolimus group. All patients were pre-treated with a standard therapy (unfractionated heparin, aspirin and clopidogrel). The use of inhibitors of GP IIb/IIIa and thrombus-aspiration were left at the discretion of physicians, however both were strongly recommended. Stent implantation was carried out according to the standard clinical practice employing low pressure stent deployment with high-pressure postdilatation using shorter, non-compliant balloon. All patients were scheduled for 9-month clinical, angiographic and OCT follow-up. Primary end-point of this study were the number of uncovered struts.

RESULTS All procedures were carried out without complications in both groups. Baseline demographic and procedural characteristic were well balanced in both groups. The rate of MACE did not differ significantly at 30 days between both groups. There was one acute stent thrombosis requiring immediate re-PCI in the everolimus stent group and one asymptomatic stent thrombosis in the biolimus group (revealed during stage PCI of non-culprit lesion). Furthermore, there was one non-cardiac death in the biolimus group. 9-month angiographic and OCT follow-up underwent 87% patients in everolimus and 90% patients in biolimus group respectively. At 9-month follow, the rate of MACE and angiographic restenosis were comparable and very low in both groups (2 vs. 1% and 1 vs 1% respectively; P=NS). All in-segment and in-stent angiographic data (reference diameter, minimal diameter, mean diameter, % stenosis) were comparable at 9-month in both groups. OCT data presents Table. The rate of uncovered struts were significantly higher in biolimus group (19.67±16.52 vs. 9.99±10.38; p=0.0001). On the other hand, there was a trend to higher mean and minimal lumen diameter (3.35mm±0.56 vs. 3.2mm±0.43; p=0.06 and 2.88mm±0.55 vs. 2.74mm±0.49; p=0.09).

CONCLUSIONS At 9-month follow-up, second generation everolimus drug-eluting stent shows better healing when compared to biolimus second generation drug-eluting stent. However, the stent struts coverage is considerably high in both groups.

CATEGORIES CORONARY: Stents: Drug-Eluting

TCT-604

Contemporary DES for high risk bleeding patients: Real world experience of the polymer-free Biofreedom stent

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BACKGROUND The Biolimus A9 coated Biofreedom stent is a polymer free stainless steel drug eluting stent. In an animal models 98% of the drug has diffused into the vessel wall in 1 month and it is reasonable to consider short term DAPT of 1 month for patients with this stent. Moreover, Biofreedom stent would be ideal in patients who may not tolerate 12 months of DAPT therapy. The aims of this study was to evaluate the indications, safety, efficacy and medium term outcome of real world patients who had PCI using Biofreedom stent and short term DAPT therapy.

METHODS The cardiac interventional center at the Royal Bournemouth Hospital, UK has been one of the leading recruiting centers in the world for the Biofreedom stent LEADERS Free trial. After the recruitment period was complete, open label Biofreedom stent was incorporated in selected PCI cases who had high risk of bleeding and would benefit from short term DAPT therapy. The indication for PCI, procedural details, images, equipment used, complications and follow up details were recorded and analyzed.

RESULTS From August 2014 - May 2015, 1690 stent cases were identified of which Biofreedom stent was used in 60 cases (3.6%). Mean age of these 60 was 76.6+/-10.5 years, 41 (68%) were males. The indication for PCI was STEMI 4 (6.7%), Non-STEMI 18 (30%), unstable angina 5 (8.3%), stable angina 21 (35%) and staged procedure in 12 (20%) patients. Left ventricular systolic function was normal in 56.6%, mildly impaired 6.6%, moderately impaired 21.6% and severely impaired in 6.6%. A Biofreedom stent was selected during PCI in view of concomitant warfarin therapy in 27 (56.5%), elderly age 9 (15%), awaiting noncardiac surgery 8 (13.3%), anemia 3 (5%), bleeding issues 9 (15%) and due to poor compliance of medication in 4 (6.6%). Stent was deployed in LMS in 2, LAD 34, circumflex 17, RCA in 12 and 2 in venous graft. The lesion was predilated in 48 (80%) of cases and rotablation and laser atherectomy was performed prior to stent deployment in 8 (13.3%) and 3 (5%), respectively. The mean stent diameter was 3.08+/-0.40mm and length 35.8+/-18.8mm. No major complications was recorded during the stent deployment 1 month DAPT therapy was advised in 55 (91.6%), 6 months in 1 and 12 months in 4 patients. Patients were followed up for a period of 160+/-84 days. Fifty three (88%) had a good medium term outcome. Five (8.3%) died during the follow up period (4 patients with either cardiogenic shock, ventilated primary PCI and VT). One patient each developed restenosis and subacute stent thrombosis (Biofreedom deployed after laser PCI for underexpanded stent).

CONCLUSIONS The use of very short term DAPT with the Biofreedom stent in patients at high risk of bleeding events was associated with event free survival of 88% within this small case series. When prolonged DAPT is contraindicated, Biofreedom offers an alternative solution to conventional DES and

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Biolimus, BioMatrix family products, Bleeding

TCT-605

Serial C-reactive Protein Measurement-Based Assessment Of Long-term Outcomes Among Patients With Chronic Kidney Disease Undergoing Drug Eluting Stent Implantation

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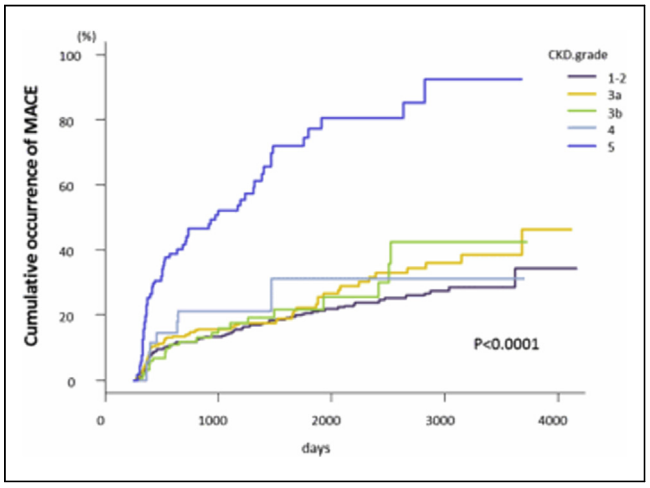
BACKGROUND Inflammation is well known as predictor of survival among patients with chronic kidney disease (CKD), and the CKD was reported as predictor of drug eluting stent (DES) stent failure. Assessment of inflammation may be helpful to understand mechanism of DES failure among CKD patients.

METHODS We investigated consecutive 1238 patients who have available paired C-reactive protein (CRP) (pre-procedure as baseline and 8-12 months later PCI as late-phase) among patients undergoing DES implantation. CRP elevation was defined as >0.2mg/dl. We divided them into 5 groups according to CKD grade (G1-2: eGFR >60ml/min; n=673, G3a:45-59 ml/min; n=308, G3b: 30-44 ml/min; n=118, G4: 29-15 ml/min; n=34, G5: <15ml/min; n=105), and investigated occurrence of major adverse cardiac event (MACE) comprised from all cause death, non-fetal myocardial infarction, target vessel revascularization, and any other unplanned revascularization.

RESULTS Prevalence of CRP elevation at baseline was increased with advance of CKD grade (G1-2; 35.0%, G3a; 32.5%, G3b; 39.0%, G4; 51.4%, and G5; 65.4%), and that was not decreased among patients with CKD G4 and G5 at late phase (vs. baseline; 18.8%: P<0.0001, 20.8%: P=0.0002, 21.2%: P=0.003, 34.3%: P=0.12, and 60.6%: P=0.58). Survival analysis revealed that MACE was frequently occurred in CKD G5 than the other (Figure), and multivariate analysis revealed that elevated late-phase CRP (HR;3.24, 95%CI; 2.46-4.26, P<0.0001), number of diseased segment (HR;1.14, 95%CI; 1.07-1.20, P<0.0001), diabetes mellitus (HR;1.41, 95%CI;1.08-1.83, P=0.01), and CKD G5 (HR;3.15, 95%CI;2.25-4.41, P<0.0001) was positive predictor of occurrence of MACE, while statin was negative predictor (HR;0.75, 95%CI; 0.56-0.99, P=0.048). Propensity score-matched analysis also confirmed effect of late-phase CRP elevation on MACE (HR: 3.50, 95% CI: 2.63-4.65, P<0.0001).



CONCLUSIONS Resistant inflammation of patients with advanced CKD may attenuate efficacy of DES.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS Inflammation, Long-term clinical outcomes

TCT-606

Early DES and BMS healing profile assessed by OCT and proteomics in a pig model

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BACKGROUND The strut coverage in OCT is used as a surrogate marker of chronic stent healing, however less data is available regarding the acute healing response in the first week.

METHODS There were 13 BMS and 15 DES implanted into the coronary arteries in an overstretch model. OCT follow-up was performed at 1, 3, 7, 14, and 28 days post implantation and assessed strut apposition, coverage and neoinitmal volume per 1 mm of stent (CAAS intravascular, Pie Medical). A proteomic approach was used to measure changes in proteins expression in the arterial neointima over time following implantation of drug-eluting (DES, Xience Pro, Abbott, USA) and same metallic platform bare-metal stents (BMS, MLVision, Abbott, USA) compared to balloon angioplasty in porcine coronary arteries.

RESULTS In the early period after implantation a higher neointimal volume per 1 mm for BMS (0.24±0.028mm3 vs. 0.25±0.024mm3; p=0.025) without differences between BMS and DES in the stent struts malapposition (6.84±2.63% vs. 8.04±2.35%; p=0.75) and in stent strut coverage (45.50±4.94% vs. 36.73±4.41%; p=0.25) was found. At 28 days post implantation the difference in in-stent neoinitmal volume per 1mm (0.70±0.13 vs. 0.68±0.02; p=0.89), struts coverage (94.844±2.89 vs. 98.931±0.51 p=0.778) and number of malapposed struts (0.866±0.52 vs. 0.407±0.40 p=0.238) were similar for BMS and DES. Animals were sacrificed at each of these time-points and their coronary arteries were retrieved with subsequent separate analysis of the vascular media and neointima (for time-point 28). A total of 145 ECM and ECM-associated proteins were identified by mass spectrometry. A comparison of the media versus neointima revealed an increase of collagens and regulatory proteins, such as small leucine rich proteins in the media, while basement membrane proteins were predominantly found in the neointima. Only by day 28, the neointima in DES compared to BMS showed increased expression of proteins involved in the regulation of calcification.

CONCLUSIONS Early healing events in first week after stent implantation involve less neointimal volume in DES and initially similar proteomic profiles for DES and BMS. After 28 days there are differences in extracellular matrix-related protens between DES and BMS. It suggest the high biocompatibility of permanent fluorinated polymer coated DES in the acute phase after implantation.

CATEGORIES CORONARY: Stents: Drug-Eluting

KEYWORDS DES

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Neointimal Transformation and Late Stent Failure from 2 months to 2 years of the New Dual Therapy Endothelial Progenitor Cell Capturing Sirolimus-eluting COMBO Stent by Longitudinal Sequential OCT: The EGO-COMBO Study

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BACKGROUND Late stent failures (late stent thrombosis, late catch-up, and accelerated neoatherosclerosis) were reported in monotherapy drug eluting stents (DES). The benefits of the new "dual" therapy endothelial-progenitor-cell capturing sirolimus-eluting COMBO stent (OrbusNeich, FL, US) were analyzed.

METHODS Four longitudinal sequential OCTs in each patient were obtained in this prospective, single center study; at baseline (for best stent optimization); at early FUs from 2-5M (4 monthly groups in 1:2:2:1 ratio for % strut coverage); at 9M (for neointima metrics), and at 24M (for neointimal changes). Clinical event adjudication & OCT analyses were performed by CRF core laboratory.

RESULTS 61 patients (33% DM and 74 lesions) received 88 COMBO stents. All 61 patients completed 9M OCT FU but 17 asymptomatic cases refused 24M OCT (FU rate 68.3%). Median strut coverage increased from 77.1, 92.5, 92.7, 94.9, 99.5, to 99.2% from 2M, 3M, 4M, 5M, 9M, to 24M, respectively. No late stent thrombosis was recorded at 36M (clinical FU rate 98.3%) and MACE rate 3.28%. Regarding late catch-up, rather, significant neointima "regression" was documented from 9M to 24M; in-stent % neointimal volume (%) 17·8 (12·2-21·2) vs 15·7 (11·2-19·4), p=0.011. Extra-stent-lumen area (Figure 2) was recorded in 31·1% (23/74) of lesions during first OCT (2 to 5M); this disappeared significantly by 9M, representing rapid vessel healing. Progressively increase in homogeneous neointima (conversion from heterogeneous & layered neointima) with reduction in peri-strut-low-density area was observed (Figure 2), representing neointimal maturation without accelerated neoatherosclerosis.

	1st OCT Follow-up					2nd OCT FU	3rd OCT FU	P-value
	2 months	3 months	4 months	5 months	P-value 2 vs 5M	9 months	24 months	9 vs. 24M
Total number of lesions analyzed	n = 12	n = 24	n = 25	n = 13	NA	n = 74	n = 51	NA
Median stent length analyzed (mm)	23·5 (21·7-36·4)	23·5 (18·8-26·6)	23·2 (18·8-24·6)	19·6 (19·0-23·4)	0·49	22·9 (18·2-25·4)	22·6 (17·8-25·0)	0·67
Total number of frames analyzed	n = 347	n = 627	n = 642	n = 300	NA	n = 1884	n = 1279	NA
Total number of struts analyzed	n = 3430	n = 6360	n = 6505	n = 2946	NA	n = 18904	n = 12822	NA
Strut coverage percentage as defined by 6 categories								
Covered (D+E+F) (%)	77·1 (67·1-84·7)	92·5 (81·9-94·3)	92·7 (86·8-95·3)	94·9 (89·6-97·6)	0·046	99·5 (97·8-99·9)	99·2 (98·6-99·8)	0·62
Uncovered (A+B+C) (%)	22·9 (15·3-32·9)	7·5 (5·7-18·1)	7·4 (4·7-13·2)	5·1 (2·4-10·5)	0·045	0·5 (0·1-2·2)	0·8 (0·2-1·4)	0·60
Strut level and frame (cross-section) level OCT analyses								
Malapposed struts (%)	0·1 (0·1-0·7)	0·4 (0·3-0·7)	0·5 (0·1-0·9)	0·4 (0·1-0·6)	0·64	0·1 (0·1-0·5)	1·3 (1·3-1·3)	NA
Neointimal thickness (mm)	0·04 (0·00-0·06)	0·04 (0·03-0·07)	0·04 (0·03-0·07)	0·04 (0·03-0·08)	0·49	0·14 (0·08-0·21)	0·12 (0·07-0·19)	<0·001
Neointimal area (NIA) (mm²)	0.56 (0.32-0.63)	0.47 (0.33-0.59)	0.55 (0.35-0.75)	0.61 (0.41-0.90)	0.44	1·34 (1·02-1·65)	1·16 (0·92-1·52)	0.001
Neointimal volume (NIV) (mm³)	13·6 (9·2-15·0)	10·2 (6·7-15·17)	13·47 (6·0-18·57)	13·7 (10·0-17·0)	0·95	29·9 (22·1-43·2)	26·2 (19·6-35·8)	0·003
Percentage NIV (%)	6·8 (3·3-8·4)	6·0 (4·2-8·0)	6·7 (5·2-7·9)	7·5 (6·3-8·9)	0·41	17·8 (12·2-21·2)	15·7 (11·2-19·4)	0·011